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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,538	10/16/2003	Igor Lifshitz	1662/61403	2120

26646 7590 05/16/2006

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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/688,538	Applicant(s) LIFSHITZ ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10, 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The levels in these claims is unclear. Is this the starting level, the final level, or some levels intermediate between the two? The "exposed valacyclovir". would cover the material at the start, and the end, and at all times in between.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mudryk, JP8-164303, 20010007903, 6270788, 3989849, 3510272, 5270267 and Rasul.

The Mudryk reference teaches the method for removing residual organic solvents from a pharmaceutical drug. The technique involves placing the drug plus water, to provide water vapor, in an oven which can be kept at atmospheric pressure; see paragraph

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1 of column 2. Another technique is to pass moist nitrogen gas into the fluid bed dryer (named in the instant claim 19) at atmospheric pressure; see column 2, lines 22-25 and example 3.

Although the reference teaches removal of solvents generally, it is particularly directed to the removal of aliphatic alcohols,, named at column 1, line 12 as the specific solvent category of particular interest. The working examples are drawn to the removal of ethanol and isopropanol, the solvents named in these claims. Valacyclovir hydrochloride is not specifically named, another hydrochloride is used in example 2. However, the use of any drug would be obvious. One is motivated to try to remove alcohols from any drug prepared in alcohols (which, as the specification notes, is true for valacyclovir hydrochloride) in order to comply with the ICH standards for residual solvents, as taught by the reference at the last full paragraph in column 2.

Claims 1-16 use humid air, whereas the reference has humid nitrogen. This would be an obvious variation, given the fact that air is mostly nitrogen.

Applicants are simply applying a known technique for removing alcohols from drugs, and in particular for drugs which are hydrochloride salts. This is thus obvious.

The traverse is unpersuasive. Applicants argue that “the method disclosed by Mudryk et al. is not instantly and unquestionably recognized as a technique of general applicability”. But that “instantly and unquestionably recognized” is not the legal standard. The reference teaches what it teaches. Things are questioned in science all the time. Similarly, applicants argue that with any given drug, it might not work. This is correct. All techniques are subject to the limitation that they might not work. However, obviousness has never required absolute predictability, *In re Lamberti*, 192 USPQ 278; *In re Longi*, 225

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USPQ 645, 651; *In re Moreton*, 129 USPQ 288; *In re Kronig*, USPQ 428; *In re Wahl*, 145 USPQ 194; *In re Mehta*, 146 USPQ 284; *In re Rinehardt*, 189 USPQ 143; *In re Mochel*, 165 USPQ 319.

Applicants argue that this “method was not recognized as one of general applicability.” First, applicants present no evidence as to this lack of lack-of-recognition. Second, this is not the legal standard. A reference teaches what it teaches, without regard to the recognition that it receives.

Applicants point out that one technique of the reference “requires an atmosphere *saturated* with water vapor.” This is true, but all of the claims read on saturated as well, since no upper limit appears. Applicants then say that in another, the atmosphere is merely “moist”. The term “moist air” has no exact definition, but typically refers to a range of 50-95% RH. Applicants also argue that moist air and moist nitrogen have differences which “are not trivial”, but any differences are well known. Yes, it is true that air will support combustion far more easily than will nitrogen, but these process are not done under combustion circumstances.

Additional references demonstrate the use of this process. In JP8-164303, see the abstract. Although the translation is rough, it is clearly teaching the use of humid air to remove lower alcohols from drugs generally. In 20010007903, paragraph 0016 teaches that “moist air” is used to remove the solvent. See e.g. example 5, and note that the solvent removed is the same IPA as is listed in claim 12, and example 7 shows the fluidized bed use.

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In 6270788, see column 9, lines 34-35. In 3989849, see column 5, lines 26-29. In 5270267, see column 6, lines 19-24. In 3510272, see column 4, lines 16-20. In Rasul, see section 2.2.1, point 3.

In summary, the broad teaching is set forth by Mudryk et al. and JP8-164303. The other references provide numerous specific examples. This is a conventional technique for solvent removal.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-15 of copending Application No. 10880862. Although the conflicting claims are not identical, they are not patentably distinct from each other because these are drawn to the exact same step. The results are recited differently in the preamble, but the same actual physical step is involved. Thus, the contacting reduces the solvent concentration and thereby reduces the instability.


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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Mark L. Berch
Primary Examiner
Art Unit 1624**

5/8/2006